

REMARKS

Claims 110-139, are pending in the present application. Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. Support for these claims appears throughout the specification, drawings, and claims as originally filed. No new matter has been added.

I. *At page 2 of the Office Action, the Examiner rejects several claims under 35 USC §112, second paragraph, as being indefinite.*

These claims are not pending in the above-identified application. Accordingly this rejection is rendered moot.

II. *At page 2 of the Office Action, claims 161 and 162, have been rejected under 35 USC §102, as being anticipated by Boyce.*

There are no claims pending which correspond to claims 161 and 162. Accordingly, this rejection is rendered moot.

III. *At page 3 of the Office Action, the Examiner rejects claims 110, 111, 120-122, 124, 125, 130-133, 147, 152/124, 152/125, 152/132, 152/133, and 163 under 35 USC §103, as being unpatentable over Boyce in view of McIntyre.*

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

IV. At page 5 of the Office Action, claims 126, 137/126, 144-146, and 152/126, have been rejected under 35 USC §103 as being unpatentable over Boyce et al. in view of Burkhead et al.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. Claims 112-114, 120, and 133, 134, and 139 are directed to bone implants including adjacent, cortical bone portions with the complimentary faces on adjacent cortical bone portions including a single projection or a single depression, where the composite bone graft does not include an adhesive.

The Examiner states that Boyce et al. teach a bone-derived implant including alternating layers of cortical bone demineralized to different degrees. The sources of the bone are preferably allogenic but may also include xenogenic sources. The Examiner states that the layers are bound together mechanically or with biocompatible adhesives. The Examiner concludes that Boyce et al. teach all of the limitations of the present invention except that adjacent bone portions comprise complementary peg-like protrusions and corresponding depressions. The Examiner states that Burkhead et al. teach a glenoid prosthesis including pegs which engage gap holes to hold the lateral component of the prosthesis to the head of the scapula. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to have formed pegs which are integral with the adjacent bone portions of Boyce et al. and corresponding depressions as taught by Burkhead et al. so as to avoid the complication of additional parts during implantation. Lastly, the Examiner states that dimensioning is considered to be an obvious choice or design. In view of the following, this rejection is respectively traversed.

Boyce discloses a bone-derived implant made up of one or more layers of fully mineralized or partially demineralized cortical bone and optionally one or more layers of some other material as recited in Boyce at col. 4, lines 24-33. Boyce et al. do not teach or suggest a bone implant held together by a single projection and a single depression on adjacent cortical bone sections to provide an interlocking fit.

Burkhead et al. are directed to a glenoid prosthesis composed of polyethylene and including a pair of pegs extending from a flat medial surface where the pegs are positioned in a pair of holes drilled in a flat resected surface on the scapula head. In a first embodiment, Burkhead et al. *require* at least a pair of pegs and claim 1 recites “a plurality” of “posts.” See col. 3, line 10, the Abstract and claim 1.

In a second embodiment, Burkhead et al. discloses a metal backed glenoid prosthesis including a plastic insert having a lateral articulating surface for interacting with the humeral head, a flat medial surface having an indented edge which forms a raised medial portion, and a pair of snap fit, outwardly projecting, L-shaped protrusions. Col. 3, paragraph 5, discloses an embodiment where “...receives a bone screw for fixation to the bone. In addition, one or more posts or auxiliary screws are provided around the perimeter of the base to further stabilize the base against rocking and to prevent rotation of the base on the bone...”

it is submitted that the Examiner has not established a proper case of *prima facia* obviousness. A proper case of *prima facia* obviousness under 35 U.S.C. § 103, requires that the prior art as a whole, must suggest the desirability of making the claimed combination and provide a reasonable expectation of success. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

In the present case, Burkhead et al. do not suggest a bone implant having adjacent bone portions where the bone portions have a single complimentary protrusion and depression so as to provide an interlocking fit between the bone portions, as presently claimed. In fact, Burkhead et al. *teach away* from such an implant.

As discussed previously, the law on *teaching away* is clear and must be considered. Again, the court in *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988) held in reference to obviousness, that: “...In determining whether such a suggestion can fairly be gleaned

from the prior art, the full field of the invention must be considered for the person of ordinary skill is charged with the knowledge of the ...including that which might lead away from the claimed invention." The court in *In re Gurley*, 27 F.3d 551, 31 USPQ2d 1130 (Fed. Cir. 1994) held that "A prior art reference may be said to *teach away* when a person of ordinary skill; upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." The court in *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986), held that "A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered.

Burkhead et al. *teach away* from an implant having as single projection, as presently claimed, because Burkhead et al. teaches that at least two pegs are required to "stabilize" and to "prevent rotation." Col. 3, lines 20-23 states: "...at least two spaced pegs are provided so that the component resists rotational loading. The spaced pegs also minimize the effect of superior-inferior loading and anterior-posterior loading."

Neither of the references suggest an implant having as single projection, as presently claimed. In fact, Burkhead et al. *teach away* from such an implant. Thus, in view of this "*teaching away*" the references do not provide any "*teaching, suggestion, or motivation*" to "*combine or modify*" their teachings to arrive at the claimed invention.

Assuming *arguendo*, that some teaching, motivation, or suggestion, did exist, at most, the Examiner has only established that it would be "obvious to try," because there is no reasonable expectation of success. There is no reasonable expectation of success because none of the references taken alone or together teach or suggest that bone material could be expected to behave similar to the synthetic material of Burkhead et al. Burkhead et al. do not suggest, for example, that bone posses mechanical properties similar to those of Burkhead et al., or that bone material could achieve the desired result.

In view of the references, it is submitted that one of ordinary skill in the art would not be motivated to even investigate a bone implant including adjacent cortical bone portions having complimentary faces, each of which includes a single depression or protrusion to provide an interlocking fit between bone portions. In fact, one of ordinary skill in the art would be led away from doing so by the teachings of the references, and that even if such investigation were undertaken, there would be no expectation of success since bone material and synthetic materials are vastly different and exhibit vastly different properties including mechanical properties.

In view of the above, it is submitted that the Examiner has not established a proper case of *prima facie obviousness*. Further, it is submitted that nothing in either Boyce et al. or Burkhead et al., taken alone or together, render the claimed invention obvious within the meaning of 35 USC §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

V. At page 6 of the Office Action, claims 127, 128, 152/127, and 152/128, have been rejected under 35 USC §103 as being unpatentable over Boyce et al. and McIntyre.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

VI. At page 8 of the Office Action, claims 134, 135, 136, and 152/134, have been rejected under 35 USC §103 as being unpatentable over Boyce et al. and McIntyre as applied to claims 132 and 133 above and further in view of the following: the inclusion of both interlocking bone portions and locking pins would have been obvious as additional assurance that the multiple bone portions would remain fastened together.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

VII. At page 8 of the Office Action, claims 164-166, have been rejected under 35 USC §103 as being unpatentable over Boyce et al. and McIntyre.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

VIII. At page 10 of the Office Action, claims 137/124, 125, 127, 128, 132, 133, 134; and 158/137/124, 125, 127, 128, 132, 133, and 134, have been rejected under 35 USC §103 as being unpatentable over Boyce et al. in view of McIntyre and Coates et al.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

IX. At page 11 of the Office Action, claims 155/127 and 155/128 have been rejected under 35 USC §103 as being unpatentable over Boyce et al. and McIntyre as applied to claims 127 and 128 above, and further in view of the following considerations concerning the dimensional/shape limitations: Boyce et al. teach that different shapes may be used for different applications.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

X. At page 12 of the Office Action, claims 156/155/127 and 156/155/128 have been rejected under 35 USC §103 as being unpatentable over Boyce et al. and McIntyre as applied to claims 155/127 and 155/128 above, and further in view of Coates et al.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

It is submitted that claims 110–139 are in condition for immediate allowance and early notice to that effect is respectfully requested. The Examiner is invited to contact the undersigned at her Spotsylvania, Virginia telephone number on any questions that may arise.

Respectfully submitted,
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